INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP03/11806

A. CLASSIFICATION OF SUBJECT MATTER
Int.Cl[7] C07D405/12, A61K31/4525, A61P25/00, 25/04, 25/22, 25/24, 25/28, 43/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int.Cl[7] C07D405/12, A61K31/4525, A61P25/00, 25/04, 25/22, 25/24, 25/28, 43/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho	1926-1996	Jitsuyo Shinan Toroku Koho	1996-2003
Kokai Jitsuyo Shinan Koho	1971-2003	Toroku Jitsuyo Shinan Koho	1994-2003

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CAPLUS/MEDLINE/BIOSIS/EMBASE(STN), JSTPlus/JMEDPlus(JOIS)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 223403 A2 (BEECHAM GROUP PLC.), 27 May, 1987 (27.05.87), Page 8, example 1 & AU 8664332 A & NO 8604237 A & JP 62-129280 A & FI 8604320 A & DK 8605087 A & PT 83608 A & US 4721723 A & CA 1287060 C & CZ 9103910 A3 & ES 2058061 T3	8,9 1-7
Y	EP 812827 A1 (SUMIKA FINE CHEMICALS Co., Ltd.), 17 December, 1997 (17.12.97), Claims 4, 8 to 14 & JP 10-291975 A & US 5948914 A	1-7

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search 11 December, 2003 (11.12.03)	Date of mailing of the international search report 13 January, 2004 (13.01.04)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SUGI, K. et al., Improved synthesis of paroxetine hydrochloride propan-2-ol solvate through one of metabolites in humans, and characterization of the solvate crystals, Chemical & Pharmaceutical Bulletin, 2000, Vol.48, No.4, pages 529 to 536	1-9

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

national application No.
PCT/JP03/11806

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-7	YES
	Claims	8, 9	NO
Inventive step (IS)	Claims	1-7	YES
	Claims	8, 9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: EP 223403 A2 (Beecham Group PLC) May 27, 1987
Document 2: EP 812827 A1 (Sumika Fine Chemicals Co., Ltd.) December 17, 1997

Document 1 cited in the international search report (see Claim 1, etc.) states that hemihydrate crystals can be obtained by crystallization or recrystallization of paroxetine hydrochloride from a solvent system that contains water (see page 4, lines 16 to 20).

Document 2 describes a process for obtaining paroxetine hydrochloride by reacting (3S4R)-trans-1-tert-butoxycarbonyl-4-(4-fluorophenyl)-3-[3,4-methylenedioxyphenyl] oxymethyl] piperidine with hydrogen chloride in isopropanol (see Claim 11, etc.)

oClaims 1-7

Documents 1 and 2 above neither describe nor suggest the inventions of claims 1-7, and therefore these inventions are novel and involve an inventive step.

oClaims 8 and 9

Paroxetine hydrochloride hydrate specified by the process of its manufacture is described in the above claims of this application, but the paroxetine hydrochloride hydrate prepared by the process specified in the above claims and the paroxetine hydrochloride prepared by the process described in document 1 are one and the same, and are thus indistinguishable.

As a result, the inventions of claims 8 and 9 lack novelty and an inventive step with respect to document 1 above.

In a written reply dated August 5, 2004, the applicant asserts: "the paroxetine hydrochloride hydrate described in claims 8 and 9 is produced by a process that is different from the process for producing the paroxetine hydrochloride hydrate described in document 1 and can thus be understood to be novel and to involve an inventive step with respect to document 1 (note: typographical error in applicant's assertion corrected)."

However, when an inventive "substance" is identical to a "substance" known from prior art, it cannot be considered to be novel or to involve an inventive step even if the process for producing is different. Because the paroxetine hydrochloride hydrate in the claims of this application and the crystalline paroxetine hydrochloride hydrate described in document 1 cannot be considered to differ as "substances," this examination cannot recognize that the inventions of the above claims of this application have novelty and an inventive step.